May 12, 2015

The Honorable Fred Upton
2183 Rayburn House Office
Washington, DC 20515

The Honorable Diana DeGette
2368 Rayburn House Office
Washington, DC 20515

Dear Chairman Upton and Congresswoman DeGette:

On behalf of the fourteen undersigned organizations, we want to thank you for your leadership in launching the 21st Century Cures Initiative to improve the discovery, development, and delivery of new medical treatments. Our organizations advocate on behalf of patients that heavily rely on off-label product use, and we urge the Committee to include a provision in the final legislation that directs the Food and Drug Administration (FDA) to issue guidance that would facilitate broader dissemination of clinical information on the off-label use of approved drugs and devices. We believe this guidance would align with the overarching goal of updating our regulatory policies, and foster the transparent exchange of data that would improve treatment decisions and options, particularly for patients with chronic and complex diseases. Approximately 1 in 5 drugs is prescribed off-label, and much higher in some patient populations. Revising the current restrictions on off-label promotion would ensure that patients and their providers are fully informed on all potential treatment options.

The Food and Drug Administration (FDA) currently requires manufacturers to present specific clinical trial information to bring products to market, and the FDA is responsible for creating a tailored product label reflecting how that product has been studied and how it should be used. Unfortunately, many patients suffer from diseases where there are no FDA approved products or for which their specific clinical needs fall outside of the narrow product label. As a result, the current FDA policy around dissemination of off-label product information is inefficient and restricts the free flow of information available about these treatments.

Our organizations strongly believe that all patients should have the opportunity to receive treatment that their clinician feels is most appropriate. We therefore urge Congress to direct the FDA to issue new guidance that allows for dissemination of information on off-label product use in order to

offer more potential treatment options. We believe this type of guidance would significantly improve treatment options for patients with complex and chronic diseases. A number of specialty providers have also recognized the potential value of information included in clinical reports on off-label product use and have asserted that patients would benefit from the broader dissemination of this type of information.

As you work to finalize the 21st Century Cures legislation, we urge you to include a provision that would direct the FDA to issue new guidance that ensures that patients and their providers can access pertinent information when making critical treatment decisions. We also encourage more research that will lead to new FDA-approved indications, so that fewer medications need to be prescribed off-label.

We look forward to continuing to work with the Committee on this vital initiative. Please contact Sandie Preiss, Vice President, Advocacy and Access, the Arthritis Foundation at spreiss@arthritis.org or 202 887 2910.

Sincerely,

American Academy of Dermatology Association
American Autoimmune Related Diseases Association
Arthritis Foundation
GBS/CIDP Foundation International
Immune Deficiency Foundation
Hemophilia Federation of America
Hepatitis Foundation International
Lupus and Allied Diseases Association
Lupus Foundation of America
National Alliance on Mental Illness
National Organization for Rare Diseases
National Psoriasis Foundation
Patient Services Incorporated
Scleroderma Foundation